REMARKS

This is a full and timely response to the non-final Official Action mailed **September 1, 2005**. Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

Claim Status:

By the forgoing amendment, the specification and various claims have been amended. The amendments to the claims are made, not to limit, but to broaden the scope thereof. All claims as originally presented would have been clearly patentable over the prior art of record without amendment. Again, Applicant amends claims 1 and 11, for example, to broaden the claim scope. New claim 21 has been added. No claims have been cancelled. Thus, claims 1-21 are currently pending for further action.

Prior Art:

The only issues raised in the outstanding Office Action are rejections of the claims based on various combinations of cited prior art references. Applicant will address all such rejections in turn.

Claims 11-15, 19 and 20 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,702,254 to Zabara ("Zabara"). For at least the following reasons, this rejection is respectfully traversed.

Claim 11 recites:

> A method of treating a patient with a movement disorder, comprising:
> providing at least one system control unit;
> providing at least one catheter connected to the at least one system control unit, which catheter includes at least one discharge portion;
> implanting the at least one catheter discharge portion adjacent to at least one vagus nerve to be stimulated;
> implanting the at least one system control unit; and
> delivering at least one drug to the at least one vagus nerve, thereby affecting a movement disorder in order to at, least in part, alleviate the movement disorder of the patient being treated.

(emphasis added).

In contrast, Zabara fails to teach or suggest treating a movement disorder by delivering *at least one drug* to a vagus nerve with an implanted system control unit and catheter. Zabara only teaches applying an electrical stimulus to a vagus nerve. "Electrode leads pass from the generator through a subcutaneous tunnel and terminate in an electrode patch on the vagus nerve." (Zabara, abstract).

Consequently, Zabara fails to teach or suggest "providing at least one catheter connected to the at least one system control unit." Zabara fails to teach or suggest implanting the at least one catheter discharge portion adjacent to at least one vagus nerve." Zabara fails to teach or suggest "delivering *at least one drug* to the at least one vagus nerve, thereby affecting a movement disorder."

"A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. For at least this reason, the rejection of claim 11 and its dependent claims based on Zabara should be reconsidered and withdrawn.

Additionally, the various dependent claims cited in this rejection in fact recite further subject matter that is not taught or suggested by Zabara. For example, claim 15 recites "wherein the stimulation is drug stimulation provided by at least a neural depolarizing agent." Claim 16 recites "wherein the neural depolarizing agent is succinylcholine." In contrast, Zabara fails to teach or suggest the use of a drug that is a neural depolarizing agent, such as succinylcholine. For at least these additional reasons, the rejection of claims 15 and 16 should be withdrawn.

Claim 19 recites "sensing at least one condition and using the at least one sensed condition to automatically *adjust stimulation parameters governing the delivery of the at least one drug.*" While Zabara does not teach or suggest drug delivery, Zabara further fails to teach or suggest sensing a condition and using that condition to adjust stimulation parameters. Zabara merely teaches sensing a condition to determine whether to apply or not apply stimulation. (Zabara, abstract, last two sentences). Zabara does not suggest that sensing a condition can be used to adjust the parameters of the stimulation being applied. For at least this additional reason, the rejection of claims 19 and 20 should be reconsidered and withdrawn.

Claims 1-5, 7 and 9 were rejected as being unpatentable under 35 U.S.C. § 103(a) over the combined teachings of U.S. Patent No. 6,227,203 to Rise ("Rise") and U.S. Patent No. 6,051,017 to Loeb ("Loeb"). For at least the following reasons, this rejection is respectfully traversed.

Claim 1 recites:

> A method of treating a patient with a movement disorder, comprising:
> providing at least one implantable stimulator for controlling delivery of at least one stimulus via at least one infusion outlet, wherein the at least one stimulus comprises stimulation via *at least one drug delivered through the at least one outlet*;
> implanting the at least one stimulator entirely or substantially in the carotid sheath; and
> using the stimulator, *applying the at least one stimulus to at least one vagus nerve* in order to, at least in part, alleviate the movement disorder of the patient being treated.

(emphasis added).

In contrast, the combined teachings of Rise and Loeb teach applying a drug therapy *to the brain*. Rise and Loeb do not teach or suggest applying a stimulus, including at least one drug, to at least one vagus nerve as claimed.

Rise teaches that "electrical stimulation pulses and/or drug therapy is provided to predetermined portions of the brain to blocking [sic] neural activity." (Rise, abstract). Rise does not teach or suggest stimulating any site outside the brain. (*See*, Rise, Figs. 1 and 4-9). Loeb is cited only for the teaching of a leadless implantable miniature stimulator. (Action of 9/1/05, p. 5). Loeb does not teach or suggest applying a drug therapy to a vagus nerve as claimed. In fact, no prior art reference of record teaches or suggests this subject matter.

Consequently, the combination of Rise and Loeb fails to teach or suggest a method of treating a patient with a movement disorder using a stimulus comprising "at least one drug" and "applying the at least one stimulus to at least one vagus nerve" as recited in claim 1. "To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least this reason, the rejection of

claim 1 and its dependent claims based on the combination of Rise and Loeb should be reconsidered and withdrawn.

Various other rejections of dependent claims also were made using several combinations of different secondary references. None of the cited prior art references teach or suggest the delivery of a drug stimulus to a vagus nerve to treat a movement disorder.

Specifically, claims 6 and 8 were rejected under 35 U.S.C. § 103(a) over the combined teachings of Rise, Loeb and U.S. Patent No. 6,179,826 to Aebischer et al. ("Aebischer"). Claim 10 was rejected under 35 U.S.C. § 103(a) over the combined teachings of Rise, Loeb and U.S. Patent No. 6,464,687 to Ishikawa et al. Claims 16 and 18 were rejected under 35 U.S.C. § 103(a) over the combined teachings of Zabara and Aebischer . Claim 17 was rejected under 35 U.S.C. § 103(a) over the combined teachings of Zabara and Rise. These rejections are all respectfully traversed for at least the same reasons given above with respect to independent claims 1 and 11.

Conclusion:

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper that have not been elsewhere authorized, authorization is hereby given to charge those fees to Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

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I hereby certify that this correspondence is being transmitted to the Patent and Trademark Office facsimile number 571-273-8300 on December 1, 2005. Number of Pages: 20

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